



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 10, 2020

Bridget Middleton
Senior Regulatory Specialist I
Ecolab, Inc.
1 Ecolab Place
St. Paul, MN 55102

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: XHC-E
EPA Registration Number: 1677-254
Application Date: March 25, 2020
Decision Number: 561079

Dear Ms. Middleton:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

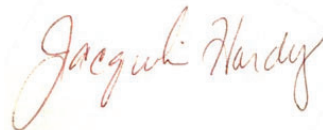
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is large non-enveloped and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Poliovirus 1 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,

A handwritten signature in red ink that reads "Jacqueline Hardy". The signature is written in a cursive, flowing style.

Jacqueline Hardy, Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: stamped label

[Note to reviewer. Wording in brackets considered optional and interchangeable.]

XHC-E

[WFI Formula] [[Made With][Water for Injection]][Blended with
WFI][Disinfectant blended with WFI]

[Gamma Irradiated] [Filtered to 0.2 microns] [0.2 Micron Filtered]

ONE-STEP DISINFECTANT / HARD SURFACE DISINFECTANT / VIRUCIDE*/VIRUCIDAL* /
SPORICIDAL / FUNGICIDE / NON-FOOD CONTACT SANITIZER

For use in [Hospitals], [Hospital Compounding Pharmacies], [Compounding Pharmacies],
[Cleanrooms], [Controlled Areas], [Pharmaceutical Manufacturing Facilities], [Biomedical
Facilities], [Biotechnology Facilities],[Medical Device Facilities],[Medical Device Manufacturing
Facilities],[Life Science Laboratories], [Industrial Facilities]

Active Ingredients:

*Sodium Hypochlorite.....0.58%

Other Ingredients:99.42%

Total:100.00%

[*Equivalent to 0.55% available chlorine]

ACCEPTED

4/10/2020

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 1677-254

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

FOR EMERGENCY MEDICAL INFORMATION CALL TOLL-FREE: 1-800-328-0026
OUTSIDE NORTH AMERICA, CALL 1-651-222-5352

PHYSICAL AND CHEMICAL HAZARDS: Strong oxidizing agent: Mixing this product with chemicals (e.g. ammonia, acids, detergents, etc.) or organic matter (e.g. urine, feces etc.) will release chlorine gas which is irritating to the eyes, lungs and mucous membranes.

[The following statement is required only for containers 5 gallons or larger.]

ENVIRONMENTAL HAZARDS: This pesticide is toxic to birds, fish, and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. (Read the label before using.)

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

USE: This product is designed specifically as a [one-step] disinfectant [cleaner] [virucide*] [fungicide] [sanitizer][sterilant][sporicidal]for use in hospital / manufacturing locations in areas such as: (NOTE TO REVIEWER: use sites to be selected from table below):

Hospitals	Hospital Compounding Pharmacies	Compounding Pharmacies
Cleanrooms	Controlled Areas	Pharmaceutical Manufacturing Facilities
Research Facilities	Biomedical Facilities	Biotechnology Facilities
Industrial Facilities	Healthcare Institutions	Biopharmaceutical
Biopharmaceutical Manufacturing Facilities	Medical Device Manufacturing Facilities	Diagnostic Manufacturing Facilities
Life Science Facilities	Animal Life Science Facilities	Pharmacies
Biomedical technology	Comparative Medicine Facilities	Laboratory Facilities

Use on hard, non-porous surfaces [in] [or] [on]: (NOTE TO REVIEWER: surfaces to be selected from table below):

Aseptic Filling Rooms	Gowning Rooms	General Manufacturing Areas
Isolators	Tables	Counters
Machinery	Floors	Walls
Hard surfaces	Non-porous hard surfaces	Transfer disinfection
Laminar Flow benches	Shelves	Transfer Hatches
Carts	Ceilings	Countertops
Laminar flow curtains	(Biosafety Level) (BSL) hoods	Equipment
Hoods	Laboratory benches	
Products in non-porous packaging for transfer disinfection.	Anywhere contamination control is required for hard, non-porous surfaces	

This product is compatible with [the listed materials] (NOTE TO REVIEWER: may select surfaces from list below). If the product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

Stainless Steel	Glass	Laminates
PVC coated mild steel	Acrylic	Vinyl
Trespa	PVC	Terrazzo
Polymeric Flooring	Epoxy-coated Flooring	Neoprene

[DISINFECTION] [ONE-STEP CLEANING / DISINFECTION] [COMBINATION DISINFECTION AND CLEANING] [HARD SURFACE DISINFECTION]

This product is ready to use. Do not dilute. This product is a one-step disinfectant cleaner on hard, non-porous surfaces in cleanrooms and controlled areas [according to the AOAC Use Dilution Test modified] [in the presence of 5% blood serum]. For heavily soiled areas, a pre-cleaning step is required. Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wiper, [coarse spray device,] or by soaking so as to wet all surfaces thoroughly. [If applying with a spray device, hold the bottle upright 6-8" from the surface. Always close the nozzle after use.] All surfaces must remain wet for a minimum of 7 minutes and then either allow to air dry or wipe dry with a [sterilized] cloth or wiper. When used as directed at a 7 minute contact time, this product is effective against:

Staphylococcus aureus (ATCC 6538)

Pseudomonas aeruginosa (ATCC 15442)

Escherichia coli (ATCC 11229)

FOR USE AS A VIRUCIDE*

This product is ready to use. Do not dilute. For heavily soiled areas, a pre-cleaning step is required. Apply solution to hard, non-porous surfaces in cleanrooms and controlled areas with a mop, cloth, [sponge], [brush], [scrubber], disposable wiper, [coarse spray device,] or by soaking so as to wet all surfaces thoroughly. [If applying with a spray device, hold the bottle upright 6-8" from the surface. Always close the nozzle after use.] All surfaces must remain wet for the required contact time indicated in the directions for use. Allow surfaces to air dry or wipe dry with a [sterilized] cloth or wiper.

VIRUCIDAL* in 5 minutes against the following viruses [according to the Virucidal Qualification Test modified][in the presence of 5% blood serum]:

*Herpes Simplex Type I Virus (Herpes) (ATCC VR-733)

*Herpes Simplex Type II Virus (Genital Herpes) (ATCC VR-734)

*Influenza A Hong Kong H3N2 Virus (ATCC VR-544)

*Rhinovirus Type 37 (ATCC VR-1147)

*Poliovirus 1 (ATCC VR-1562)

*Adenovirus (ATCC VR-5)

FUNGICIDAL in 5 minutes against *Trichophyton interdigitale* (ATCC 9533), *Candida albicans* (ATCC 10231), *Aspergillus brasiliensis* (ATCC 16404) and *Penicillium chrysogenum* (ATCC 10003) on hard, non-porous surfaces [according to the AOAC Fungicidal Test] [modified in the presence of 5% blood serum].

SANITIZATION

This product is ready to use. Do not dilute. This product is a hard surface sanitizer for pre-cleaned, hard, non-porous, non-food contact surfaces in cleanrooms and controlled areas. Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wiper, [coarse spray device,] or by soaking, so as to wet all surfaces thoroughly. [If applying with a spray device, hold the bottle upright 6-8" from the surface. Always close the nozzle after use.] Allow surfaces to remain wet for a minimum of 3 minutes and then either allow to air dry or if desired wipe dry with a [sterilized] cloth or wiper. When used as directed at a 3 minute contact time, this product is effective against:

Staphylococcus aureus (ATCC 6538)

Enterobacter aerogenes (ATCC 13048)

DIRECTIONS FOR USE AS A HARD, NON-POROUS SPORICIDE

Use only on hard, non-porous surfaces. Clean the surface to be treated of debris and organic material. Apply ready to use solution by immersion of objects in containers by covering interior surfaces of containers, or by confining (e.g. rimmed) surfaces (e.g. floors, tables, counters) that permit a continuous layer of liquid to cover the surface for the required contact time of 5 hours. This product is effective against *Clostridium sporogenes* (ATCC 3584) and *Bacillus subtilis* (ATCC 19659) [with a 5% organic soil load]. Remove used solution and entrapped soil with a clean, dry, sterile cloth. Do not use this product as a sterilant on medical devices.

DIRECTIONS FOR USE AS A DISINFECTANT WITH SPORICIDAL ACTIVITY AGAINST CLOSTRIDIUM DIFFICILE SPORES

This product kills and/or inactivates spores of *Clostridium difficile* (ATCC 43598) on hard, non-porous surfaces. This product is effective against *Clostridium difficile* spores after a 10 minute exposure time.

Directions for cleaning prior to disinfection against *Clostridium difficile* spores:

PERSONAL PROTECTION: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

CLEANING PROCEDURE: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean [sterile] cloth, mop, and/or sponge saturated with the sporicidal product. This cleaning may be accomplished with any cleaning solution, including this product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces [in patient rooms] are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

INFECTION MATERIALS DISPOSAL: Materials used in the cleaning process that may contain feces / waste are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

To disinfect against *Clostridium difficile* spores apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wiper, [coarse spray device,] or by soaking, so as to wet all surfaces thoroughly. [If applying with a spray device, hold the bottle upright 6-8" from the surface. Always close the nozzle after use.] Allow surfaces to remain wet for a minimum of 10 minutes and then either allow to air dry or if desired wipe dry with a [sterilized] cloth or wiper

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.

PESTICIDE STORAGE: Store this product in a cool, dry area, away from direct sunlight and heat to avoid deterioration. Keep this product in a tightly closed container when not in use. In case of a spill, flood area with large quantities of water. Product rinsate that cannot be used must be diluted with water before disposal in a sanitary sewer.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING AND DISPOSAL:

[For containers 5 gallons or less]

Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

[Lot Number / Batch Code XXXXXX

EXPIRY: Day/Month/Year]

US EPA Reg. No. 1677-254

US EPA Est. No.: 001677-GBR-001, 5389-NC-1 (G)

DIN 02458098

Net Contents: 800 mL (27.1 fl oz)
887 mL (30 fl oz)
946 mL (32 fl oz)
33.8 fl oz (1L)
1 US gal (3.78 L)
1.32 US gal (5L)

Manufactured by:

Ecolab Inc.

1 Ecolab Place

St. Paul, MN 55102

USA

(Made in Great Britain) (Made in USA) (Made in United States of America)

[See [back], [side], [inside], [other] [fold-out] [booklet] [label] [panel] for [complete] [additional] [directions for use] [precautionary statements] [and] [first aid]

This product may be patented | Ce produit peut être breveté | Este producto puede ser patentado: www.ecolab.com/patents

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(Si no puede leer en inglés, pregunte a su supervisor sobre las instrucciones de uso apropiadas antes de trabajar con este producto.)

Optional Claims (Marketing Claims)

- [Gamma Irradiated] [Disinfectant][Sporicidal][product]
- [Sterile] [Validated 10⁻⁶ SAL (Sterility Assurance Level)]
- [RTU][Ready to Use][disinfectant][solution][product] [containing sodium hypochlorite] [for hard, non-porous surfaces][for use in cleanrooms and controlled areas]
- [Ready to use][hard, non-porous surface][disinfectant][solution][containing sodium hypochlorite]
- [Active Chlorine] [Solution][Disinfectant][product]
- Disinfectant solution
- [This] [product][Disinfectant] [Active Chlorine Disinfectant] [Active Chlorine Ready To Use solution] [Active Chlorine product] has broad spectrum activity, [controlling microbial contamination likely to be found in a cleanroom environment,] [including difficult bacterial spores]
- Easy to use
- [This] [product][Disinfectant] [Active Chlorine Disinfectant] [Active Chlorine Ready to Use solution] [Active Chlorine product] is non-corrosive [so it can be used in most cleanroom [cleaning][and][disinfecting] applications]
- [This] [product][Disinfectant] [Active Chlorine Disinfectant] [Active Chlorine Ready to Use solution] [Active Chlorine product] [is a gamma irradiated sodium hypochlorite solution][containing 0.55% (5500ppm) available Chlorine][available in a [800mL][30 oz][32 oz][1 liter trigger spray or [1 gallon][5 liter] capped container]
- [This] [product][Disinfectant] [Active Chlorine Disinfectant] [Active Chlorine Ready to Use solution] [Active Chlorine product] [is filtered with a 0.2 micron filter,][capped and filled]in a [Grade A (ISO Class 5)] cleanroom [and then [and double bagged in a Grade C (ISO Class 7) cleanroom before gamma irradiation]
- [This] [product][Disinfectant] [Active Chlorine Disinfectant] [Active Chlorine Ready to Use solution] [Active Chlorine product] is [double bagged] [and gamma irradiated]
- Double bagged [for easy transfer into Grade A and B (ISO Class 5 and 6) cleanrooms]
- Product is gamma irradiated
- Broad spectrum of antimicrobial activity [including spores]
- It has broad spectrum of antimicrobial activity [including spores and both enveloped and non-enveloped viruses]
- Application Areas: For use on floors, walls and hard, non-porous surfaces [in cleanrooms and controlled areas]
- For use on floors, walls and hard, non-porous surfaces
- Broad Spectrum Activity
- Broad Spectrum Activity, including sporicidal, bactericidal, sanitizing, fungicidal and Virucidal* activity
- Sporocidal Activity
- Bactericidal Activity
- Fungicidal Activity
- Virucidal Activity

- Sanitizing Activity
- [This] [product][Disinfectant] [Active Chlorine Disinfectant] [Active Chlorine Ready to Use solution] [Active Chlorine product] can be used as part of a rotation with other disinfectants

Manufacturing claims:

- Manufactured by a ISO [9001:2008][9001:2015]
- [Certificate of analysis] [Certificate of conformity] [Certificate of irradiation] [Certificate of analysis and sterilization is included with every batch
- [This] [product][is][filtered with a 0.2 micron filter][to remove [particulates][particles] from end use product]
- [This] [product] is manufactured in cleanrooms for use in cleanrooms.
- [This] [product] [is made in accordance to the principles of Good Manufacturing Practices]

(NOTE TO REVIEWER: The following statements are for use on product sell sheets.)

- Ready to use, can be sprayed directly onto the surface.
- Ready to use – apply directly onto surface – for optimum results also wipe
- For optimum results, wipe the surface to physically remove any contaminants.

(NOTE TO REVIEWER: The following statements are for use on product sell sheets.)

Apply directly onto hard, non-porous surfaces using a cleanroom low particulate wipe or mop to ensure complete coverage. Allow contact time and then wipe dry.

Where residues must be totally eliminated, wipe down with alcohol or water of suitable quality.

Use disinfectants safely. Always read the label and product information before use.



Emerging Viral Pathogens

“This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.”

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large, Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label</i>
Enveloped virus	Poliovirus 1
Large, non-enveloped virus	Poliovirus 1

Acceptable claim language:

XHC-E has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, XHC-E can be used against [name of emerging virus] when used in accordance with the directions for use against Poliovirus 1 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. XHC-E kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Poliovirus 1 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.